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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,189	12/02/2003	Berkley Lynch	053529-5007-01	4272
9629	7590	03/05/2008		
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER WANG, CHANG YU	
			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,189	Applicant(s) LYNCH ET AL.	
	Examiner Chang-Yu Wang	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93-102, 139-154, 156 and 174-189 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 93-102, 139-154, 156 and 174-189 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/07 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 11/9/07 is acknowledged. Claims 1-92, 103-138, 143, 155, and 157-173 are cancelled. Claims 93, 139, 153, 156, 180, 184 and 186 are amended. Claims 93-102, 139-142, 144-154, 156 and 174-189 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 11/9/07 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 93-102, 139-142, 144-154, 156 and 174-189 under 35 U.S.C. 103(a) for being unpatentable over WO2003016475 (published Feb 27, 2003,

effective filing date Aug 14, 2001) in view of Margineanu et al. (Antiepileptic Drugs, 5th edition. Levy RH et al. 2002; Lippincott Williams & Wilkins, Philadelphia, PA. P.419-427, as cited in IDS submitted 09/23/04) and Berkower (Curr. Opi. Biotech. 1996.7:622-628) is withdrawn in response to Applicant's arguments.

Claim Rejections/Objections Maintained

In view of the amendment filed on 11/9/07, the following rejections are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 93-102, 139-142, 144-154, 156 and 174-189 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound that binds a levetiracetam (LEV) binding site (LBS) of SV2A protein (wild type), does not reasonably provide enablement for identifying a compound that binds a levetiracetam binding site (LBS) of all forms of SV2 proteins or all variants of all forms of SV2 proteins as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The rejection is maintained for the reasons made of record in office action mailed 6/27/07, and as follows.

At p. 10 of the response, Applicant argues that independent claim 93 is enabled because it is known that LEV binds to the LBS of a SV2 protein and thereby can be used as a control. At p. 11 of the response, Applicant argues that the claimed methods are enabled because the specification teaches binding assays and competition assays using LEV binding to an SV2 protein control. Applicant argues that the previous office action states that identification of a compound binding to an SV2A/B/C is enabled and Applicant also provides support that SV2C also binds LEV as disclosed in US 20050137241 and that SV2A to SV2B and SV2C are structurally and functionally similar as taught by Janz et al. (Neuroscience 1999. 94:1279-1290). Applicant's arguments have been fully considered but they are not persuasive.

In response, although Applicant is enabled for identifying a compound binding to SV2A/B/C, the instant claims are not directed to determination of binding assays that compounds bind to a SV2 protein. But rather, independent claims 93 and 156 are directed to a method of identifying a compound that binds a LBS of an SV2 protein. However, it is noted that the steps recited in instant claim 93 do not include a limitation that the test compound binds to SV2 in the presence of LEV to compete with the binding of LEV to the LBS of SV2 protein. Since the claimed method is to determine whether a compound binds to LBS, it would require the presence of LEV to determine whether the test compound would bind or replace the binding of LEV to LBS of an SV2 protein. A simple binding assay without the presence of LEV cannot determine whether the test compound would bind to LBS of SV2 protein because the test compound can still bind to any site of SV2 protein without binding to the LBS of SV2 protein. Thus, the claimed

method recited in instant claims 93 and 156 are not enabled because a skilled artisan cannot determine whether a test compound would bind to LBS of a SV2 protein without the presence of LEV. In addition, as previously made of record, although SV2A/B/C are structurally and functionally similar, the instant specification fails to teach whether all of the SV2 proteins contain LBS, and thereby can be used in the claimed method. Further, SV2A, 2B and SV2C have different activity and biological property; for example, botulinum neurotoxin A (BoNT/A) can interact with SV2C but not SV2A and SV2B (Mahrhold et al. FEBS Lett. 2006. 580: 2011-4, cited in a prior office action.). Thus, it is unpredictable whether the results obtained from SV2A would be the same as in all SV2 proteins or other SV2 proteins as recited in instant claims 102, 142 and 185 or variants as recited in instant claims 176, 181 and 187. The specification fails to teach what specific regions of all SV2 proteins comprise the LEV binding sites. The specification also fails to provide sufficient guidance as to what specific conservative amino acid substitutions would preserve the activity of SV2A. Thus, it is unpredictable whether other SV2 proteins or variants of all SV2 proteins can be used in the claimed method. The original specification only teaches LEV binds to SV2A but fails to disclose that LEV is also bind to SV2B/C. Although US20050137241 (filed on Nov 30, 2004) supports that SV2C also binds to LEV, the published document was published in 2005, which is a post-filing document. The criteria to determine whether the claims are enabled are based on the time that the application was originally filed. Thus, based on the specification as originally filed, Applicant is only enabling for identifying a compound that competes with the binding of LEV to SV2A protein.

Obviousness-Type Non-Statutory Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 93-102, 139-142, 144-154, 156 and 174-189 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 9-12, 17-19, 22-25, 29, 35, 37-40, 45-52, 54-57, 61-68, 71-74, and 78 of copending Application No. US/10/308,163 ('163), which has been issued as US Patent No. 7090985, for the reasons made of record in the office action mailed 6/27/07, and as follows.

Applicant argues that the instant claims are distinct from the claims of the '985 patent because the claims of the '985 patent do not require a step of obtaining a cell-free or membrane-free SV2 protein and the step is not routine practice (p. 13).

Applicant's arguments have been fully considered but they are not persuasive.

In contrast, as previously made of record, a method of screening for a compound using a cell-free/membrane-free polypeptide in a cell-free assay is a routine practice in

the art for a high-throughput screening as evidenced by WO2003016475 (see p. 969-967). Thus, the claimed method of using cell-free or membrane free SV2 protein in the instant application is obvious over the '985 patent. In addition, although the claims of the '985 patent recite identifying a binding partner for SV2A, the preferred species or working example in the specification include identifying ucb 30889 at the SV2A leviraetam binding site, which is the same species and anticipates the instant claims. While language is not identical, the instant claims of the instant application and the claims of the '985 patent claim an invention substantially overlapping in scope. The rejection of claims 93-102, 139-142, 144-154, 156 and 174-189 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29, 35, 37-40, 45-52, 54-57 and 61 of '163 (claims 1-24 of US Patent No. 7090985) is maintained of record until a terminal disclaimer is filed.

Conclusion

7. NO CLAIM IS ALLOWED.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Application/Control Number:
10/725,189
Art Unit: 1649

Page 9

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
January 28, 2008

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud